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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,115	08/30/2001	Carl Risinger	524592002100	9958

7590

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 12/17/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/943,115

Applicant(s)

RISINGER ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***ELECTION/RESTRICTION***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8, drawn to CYP3A4 oligonucleotides and primer pairs, classified in, at least for example, class 536, subclasses 24.31 and 24.33.
  - II. Claims 9-13, drawn to CYP2C9 oligonucleotides and primer pairs, classified, at least for example, in class 536, subclasses 24.31 and 24.33.

1. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are drawn to patentably distinct products. While each Group is drawn to nucleic acid molecules (specifically, to oligonucleotides and primer pairs), the Inventions are drawn to molecules that detect and amplify structurally and functionally distinct genes. The CYP3A4 and CYP2C9 genes have different sequences, and encode proteins with different functional properties. A reference against one molecule would not be a reference against the other. Accordingly, the products of Invention I are patentably distinct from those of Invention II.

**Election Requirement Applicable to Group II**

2. Group II is drawn to primer pairs and oligonucleotides that amplify/detect one of 5 different polymorphisms in CYP2C9. These 5 different polymorphisms are structurally distinct, being in different locations within CYP2C9 and having and being flanked by different nucleotide sequences. Further, the specification does not disclose that the different polymorphisms and molecules including them are functionally equivalent (e.g., that the polymorphisms have an identical effect on CYP2C9 expression and/or activity). The different polymorphisms are not obvious variants of one another; a reference

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against one would not be a reference against another. Accordingly, **if Group II is elected, Applicant is further required to elect** a single one of the CYP2C9 polymorphisms of the claims, and the primer pairs and oligonucleotides corresponding thereto. Both the elected polymorphism and the particular SEQ ID Nos corresponding to the elected primer pairs and oligonucleotides should be clearly identified.

**This is not an election of species.** Applicant is advised that examination will be restricted to only the elected polymorphism.

3. Because Inventions I-II, as well as the numerous distinct polymorphisms of Group II, require different sequence and text searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner, and therefore restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

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703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long horizontal flourish.

Diana B. Johannsen  
December 15, 2002